CDC/JBH/DM

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	19.07.06

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
6395-68278-02	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2005/011086	01.04.2005	02.04.2004

Applicant
THE GOVERNMENT OF THE UNITED STATES OF... et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Eich, M Tel. +49 89 2399-7578

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 6395-68278-02	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2005/011086	International filing date *(day/month/year)* 01.04.2005	Priority date *(day/month/year)* 02.04.2004

International Patent Classification (IPC) or national classification and IPC
INV. A61M11/00 B05B17/06

Applicant
THE GOVERNMENT OF THE UNITED STATES OF... et al.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 8 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08.06.2006	14.07.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Borowski, A Telephone No. +49 89 2399-2758

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/011086

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-28	as originally filed
Claims, Numbers	
1-63	received on 09.06.2006 with letter of 07.06.2006
Drawings, Sheets	
1/17-17/17	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 26-58

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 26-58

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☐ neither restricted the claims nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-25,59-63 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-25,59-63
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-25,59-63
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-25,59-63
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 58 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: *a method of using an aerosolizing device for administering an aerosolized agent to a patient.* For said claim no international search report had been established and, consequently, no examination has been carried out with respect to the novelty, inventive step and industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

The applicant had not paid the additional search fees for claims 26-57, therefore no international search report has been established for said claims. Consequently, the present written opinion does not cover said claims 26-57 (PCT Guidelines 17.60).

Re Item IV

Lack of unity of invention

This International Preliminary Examination Authority considers that there are the following 3 (groups of) inventions claimed in the international application:

i) claims 1-25 and 59-63, which essentially define an aerosolizing element comprising a movable element being capable of moving in response to an external force;

ii) claims 26-41, which essentially define an aerosolizing device including a disposable aerosolizing element being removable from the housing of the aerosolizing device;

iii) claims 42-57, which essentially define an aerosolizing device including a disposable aerosolizing element, wherein the element prevents the agent to be expelled, from contacting an actuator.

These 3 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features are:

- between claim 1 and any of claims 26 or 42: a removable aerosolizing element capable of expelling an aerosolized agent ;

- between claims 26 and 42: an aerosolizing device comprising a housing, a disposable aerosolizing element capable of expelling aerosolized agent, an oscillator/actuator positioned to exert vibratory oscillations on a portion of the disposable aerosolizing element to aerosolize agent in the element, and a patient interface shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient.

An aerosolizing element and an aerosolizing device according to these features, however, are known from the document US2003/0164169 (see figures 4A-4C for example).

The features of each group which are not common with any of the other groups address different objective technical problems. Said problems may be regarded as being:

i) how to provide dose of an agent for aerosolization, which can be stored and aerosolized in a convenient way;
ii) how to provide a compact aerosolizing device;
iii) how to prevent contamination of the aerosolizing device.

Consequently, the single general concept in the present case is not novel (and hence non inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP-A-1 149 602 (MICROFLOW ENGINEERING SA) 31 October 2001 (2001-10-31)

1. Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows a removable (column 10, lines 49-52) aerosolizing element (5) suitable for use in an aerosol delivery device (1), comprising:
a body (8, 18) having an exterior surface and a chamber (9) defined therein;
an inlet (7) defined in the body for connection to a source of agent, the inlet being in fluid communication with the chamber;

agent releasing orifices (14, 15) defined in the body an in communication with the chamber;
a moveable element (8, 8a) having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the outer surface to expel agent in the chamber through the orifices (column 7, lines 34-39); and
projections disposed in the chamber and being configured to contact the inner surface of the inner surface opposing to the moveable element (the portions of the substrate (18) surrounding the cavities (13) are considered as projections).

The subject-matter of claim 1 differs from this known aerosolizing element in that the projections are configured to contact both: the inner surface of the moveable element and the opposing inner surface when the external force is applied to the exterior surface.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to maintain a minimum spacing between the moveable element and the orifices, to maintain adequate capillary head without undue pressure loss.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT). Such solution is neither disclosed nor suggested by any of the available prior art documents. Especially D1 is silent as to whether the portions of the top substrate (18) surrounding the cavities (13) are capable of contacting the bottom substrate in use to maintain a minimum spacing in the chamber.

2. Claims 2-24 and 59-63 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

1. The independent claim 1 has not been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.

2. The features of the claims have not been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. Claims 24, 25 and 59-63 have not been numbered as required by Rule 6.4(c) PCT.

Re Item VIII

Certain observations on the international application

Claim 61 defines a product in terms of the process by which the product is made. The claim should have been constructed as a claim to the product per se that possesses the characteristics derived from the manufacturing process stated in the claim.

We claim:

1. A removable aerosolizing element for use in an aerosol delivery device for aerosolizing an agent, comprising:

a body having an exterior surface and a chamber defined therein;

an inlet defined in the body for connection to a source of agent, the inlet being in fluidic communication with the chamber;

agent releasing orifices defined in the body and in communication with the chamber;

a movable element having an inner surface that defines a portion of the chamber, the movable element being capable of moving in response to an external force applied to the exterior surface to expel agent in the chamber through the orifices; and

projections disposed in the chamber and maintaining a minimum spacing between the movable element and the orifices, the projections being configured to contact the inner surface of the movable element and an opposing inner surface of the chamber defining said orifices to maintain the minimum spacing when the external force is applied to the exterior surface.

2. The aerosolizing element of claim 1, wherein the movable portion is deformable, and the movable portion deforms under the external force to increase pressure in the chamber, thereby expelling agent from the chamber through the orifices.

3. The aerosolizing element of claim 1, wherein the movable element comprises a flexible diaphragm.

4. The aerosolizing element of claim 1, wherein the chamber includes an internal passageway portion in communication with the inlet and a main chamber portion generally opposite the orifices.

5. The aerosolizing element of claim 1, wherein the chamber is filled with a predetermined quantity of agent and the inlet is sealed.

6. The aerosolizing element of claim 1, further comprising a cover positioned over the inlet to reduce entry of undesired material into the chamber.

7. The aerosolizing element of claim 1, wherein the body comprises an orifice plate partially bounding the chamber generally opposite the movable element, the orifice plate defining the orifices.

8. The aerosolizing agent of claim 7, wherein the orifice plate consists essentially of a metal foil.

9. The aerosolizing element of claim 1, wherein the chamber can be filled with agent via gravity feed from the inlet.

10. The aerosolizing element of claim 1, wherein the chamber can be filled with agent via capillary action.

11. The aerosolizing element of claim 1, wherein the projections are dimensioned to contact the inner surface of the movable element and the opposing inner surface of the chamber when the external force is not applied to the moveable element.

12. The aerosolizing element of claim 1, wherein the external force applied to the movable member comprises vibratory oscillations causing the movable member to reciprocate and alternatingly increase pressure in the chamber to expel agent and decrease pressure to draw additional agent into the chamber.

13. The aerosolizing element of claim 1, wherein the element is pre-filled with at least a first component and a second component of an agent to be aerosolized that are mixed within the element prior to aerosolization.

14. The aerosolizing element of claim 13, wherein body comprises a first reservoir pre-filled with the first component of the agent, a second reservoir pre-filled with the second component of the agent, and a separation element disposed between the first and second reservoirs and separating the first component from the second component, the separation element being movable into the first reservoir to allow mixing of the first and second components.

15. The aerosolizing element of claim 1, wherein the body includes a needle portion shaped to receive a vial of agent and wherein an end of the needle defines the inlet.

16. The aerosolizing element of claim 1, wherein the element is disposable after use.

17. The aerosolizing element of claim 1, wherein one side of the body is adapted for direct attachment to a patient interface for conveying aerosolized agent from the orifices towards a patient.

18. The aerosolizing element of claim 1, wherein the chamber includes an air vent separate from the inlet.

19. The aerosolizing element of claim 1, wherein:

the aerosol delivery device comprises an actuator that applies the external force to the movable element to cause the agent to be expelled through the orifices; and

the body is configured to prevent the agent from contacting the actuator.

20. The aerosolizing element of claim 1, further comprising at least one airflow passageway extending through the body such that air flowing through the passageway can carry the expelled agent away from the element.

21. The aerosolizing element of claim 20, wherein the airflow passageway comprises an inlet defined in one side of the body and an outlet defined in an opposing side of the body, the outlet being offset from the inlet.

22. The aerosolizing element of claim 1, wherein the body comprises first and second reflective surfaces positioned on opposite sides of the orifices such that a light beam passing through the element is reflected by the first reflective surface to extend in front of the orifices and onto the second reflective surface, which reflects the light beam back through the element.

23. The aerosolizing element of claim 22, wherein the body comprises a transparent material that transmits the light beam.

24. The aerosolizing element of claim 3, wherein the flexible diaphragm comprises a plurality of projections that maintain a minimum chamber thickness.

25. The aerosolizing element of claim 3, wherein the body comprises an opening adjacent the flexible diaphragm, the opening being adapted to receive an actuator for coupling to the flexible diaphragm and applying the external force.

26. An aerosolizing device, comprising:

a housing sized and shaped to be held in a hand of a user;

a disposable aerosolizing element disposed in the housing and capable of expelling aerosolized agent;

an oscillator disposed in the housing and positioned to exert vibratory oscillations on a portion of the disposable aerosolizing element to aerosolize agent in the element; and

a patient interface coupled to the housing and shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient,

wherein the disposable aerosolizing element is removable from the housing for installation and disposal.

27. The device of claim 26, further comprising a compressed air source configured to supply compressed air to the device to assist in delivery of aerosolized agent through the patient interface.

28. The device of claim 27, wherein some of the air conveyed by the compressed air source is directed to cool the oscillator.

29. The device of claim 26, further comprising air inlet holes positioned to allow entry of atmospheric air into the device to assist in delivery of aerosolized agent through the patient interface.

30. The device of claim 26, wherein the disposable aerosolizing element has an internal chamber at least partially defined by a flexible portion that can be manually squeezed by a user to create a negative pressure within the chamber to assist in filling the chamber with agent.

31. The device of claim 26, wherein the disposable aerosolizing element has an inlet for receiving an agent to be aerosolized and prevents the agent from contacting the oscillator.

32. The device of claim 26, further comprising:

a body-mountable pack that is worn or carried on the user's body; and

a power source for the device comprising one or more batteries disposed in the pack.

33. The device of claim 32, further comprising an air pump disposed in the pack and an air conduit fluidly connecting the air pump to the housing, the air pump being operable to supply compressed air to the housing to assist in delivery of aerosolized agent through the patient interface.

34. The device of claim 32, wherein the pack is worn around the user's waist or on the user's shoulder.

35. The device of claim 26, wherein the patient interface comprises a disposable mask shaped to fit around the mouth and nose of the patient.

36. The device of claim 35, wherein the mask comprises a material that is porous to air.

37. The device of claim 26, wherein the patient interface comprises a one-way valve that is operable to permit flow from the disposable aerosolizing element to the patient through the patient interface, and to inhibit flow in the reverse direction through the patient interface.

38. The device of claim 37, wherein the one-way valve comprises a duckbill valve.

39. The device of claim 26, wherein the patient interface comprises one or more baffles that shield the disposable aerosolizing element from expired particles.

40. The device of claim 26, further comprising an aerosolization rate monitor that is operable to detect the rate at which agent is aerosolized by the aerosolizing element.

41. The device of claim 26, further comprising a counting device that is operable to record the number of doses that are administered by the device.

42. A handheld aerosolizing device, comprising:

a disposable aerosolizing element capable of expelling aerosolized agent;

a battery-powered actuator positioned to exert vibratory oscillations on a portion of the disposable aerosolizing element to aerosolize agent in the element; and

a patient interface shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient,

wherein the aerosolizing element prevents the agent from contacting the actuator.

43. The device of claim 42, wherein a fluid passageway from a source of agent to the patient interface is substantially contained within the aerosolizing element and the element is separately removable from the device.

44. The device of claim 43, wherein the source of agent is contained within the aerosolizing element.

45. The device of claim 43, wherein the aerosolizing element is shaped for direct connection to the source of agent.

46. The device of claim 42, wherein the aerosolizing element is pre-filled with a volume of agent.

47. The device of claim 46, wherein the volume of agent is sufficient for delivery of multiple single doses.

48. The device of claim 47, further comprising a vial containing agent for direct coupling to the aerosolizing element.

49. The device of claim 42, wherein the patient interface comprises a mask intended for disposal after each use.

50. The device of claim 42, wherein the patient interface comprises a mask intended for disposal after each use that is porous and entraps expired aerosols from the patient.

51. The device of claim 42, wherein the patient interface is a nasal prong intended for disposal after each use.

52. The device of claim 42, further comprising an aerosolization rate monitor that allows monitoring of aerosolizing rates during use.

53. The device of claim 52, wherein the aerosolization rate monitor comprises a light source operable to project a light beam that extends through aerosol droplets being expelled by the aerosolizing element and a light detector operable to detect the obscuration of the light beam caused by the aerosol droplets.

54. The device of claim 53, wherein the aerosolization rate monitor comprises a controller and a visual indicator, wherein the controller receives the signal from the light detector and determines an aerosolization rate based on the signal, and the visual indicator provides a visual indication regarding the aerosolization rate.

55. The device of claim 53, wherein the aerosolizing element comprises first and second reflective surfaces, the first reflective surface being positioned to reflect the light beam from the light source to extend in a first direction through the aerosol droplets, the second reflective surface being positioned to reflect the light beam extending through the aerosol droplets to extend in a second direction toward the light detector.

56. The device of claim 42, wherein at least the aerosolizing element and the oscillator are arranged together in a housing sized for holding in a hand of user.

57. The device of claim 42, further comprising a component separate from the housing in which at least batteries are positioned, the component having a power connection to the housing and adapted to be worn or carried on a user's body.

58. A method of using an aerosolizing device, the method comprising administering an aerosolized agent from the aerosolizing device by applying vibratory

oscillations to a disposable aerosolizing element in the aerosolizing device and disposing of the aerosolizing element after administering the agent.

59. The aerosolizing element of claim 1, wherein the projections are formed on the moveable element.

60. The aerosolizing element of claim 1, wherein the projections have a height of about 0.1 mm equal to the minimum spacing of the chamber.

61. The aerosolizing element of claim 1, wherein the orifices are formed by laser drilling.

62. The aerosolizing element of claim 1, wherein the projections are configured to allow agent to flow through the chamber when the projections are in contact with the inner surface of the movable element and the opposing inner surface of the chamber.

63. The aerosolizing element of claim 1, in combination with the aerosol delivery device, the aerosol delivery device comprising an ultrasonic horn coupled to the moveable element and comprising an actuator and a motion transmitting member coupling the actuator to the moveable element for transferring vibratory motion of the actuator to the moveable element.